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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 08/909,130 | 08/11/1997 | JAMES E. COX | 33019/138/10 | 1242 |
| 28075 | 7590 | 12/14/2004 | EXAMINER | |
| CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420 | | | DESANTO, MATTHEW F | |
| | | ART UNIT | PAPER NUMBER | |
| | | 3763 | DATE MAILED: 12/14/2004 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|-------------------------------|------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 08/909,130 | COX ET AL. | |
| | Examiner Matthew F DeSanto | Art Unit 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 March 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 4,5 and 10-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____

- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____

DETAILED ACTION

1. In view of the appeal brief filed on March 26, 2004, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 4, 5, 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Crocker (USPN 5,522,800).

Crocker discloses an elongated catheter, a balloon with an inflatable envelope portion, perfusion lumen that includes a metallic ribbon coil support, as well as wherein the perfusion lumen has a guidewire lumen therein (Figures 4-6 and 14, 15).

Figures 4-6 and 14, 15 show the balloon inflated and deflated. The perfusion lumen starts at holes 154 (or section ref #. 39) and ends at holes 152 (section ref #. 37). The guide wire can enter at the proximal section of the catheter and travel through the perfusion lumen and exit at the distal end. The perfusion lumen decreases in cross section as can be seen in figure 5 & 15 at the distal end. The guidewire lumen is also collapsible as taught throughout the reference since the guidewire lumen is in the collapsible tube 13 as shown in the figure 4-6.

4. Claims 4, 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Songer et al. (USPN 4,892,519).

Songer et al. discloses an elongated catheter, a balloon with an inflatable envelope portion, perfusion lumen that includes a metallic ribbon coil support, as well as wherein the perfusion lumen has a guidewire lumen therein (Figures 1, 2).

The perfusion holes start the perfusion lumen.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 4, 5, and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conway et al. (USPN 4,877,031) and further in view of Uldall et al. (USPN 5,106,368).

Conway et al. discloses the use of a perfusion dilatation catheter that comprises a guidewire lumen, a perfusion lumen (22, 30, 31), a balloon (13), wherein the perfusion lumen includes metallic ribbon coil support (shown in figure 1), but Conway et al. fails to disclose the use of a collapsible tube for the guidewire lumen (Figure 1).

Uldall et al. discloses the use of collapsible lumens for percutaneous insertion into the balloon vessel so the catheter will have the smallest possible diameter to enter into a clogged vessel for treatment. (Column 2, lines 51-67)

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the apparatus of Conway et al. with the teachings of Uldall et al. because Uldall et al. taught the use of a collapsible lumens to decrease the overall diameter of a catheter which is beneficially to all catheters especially catheters that used for angioplasty.

Response to Arguments

7. Applicant's arguments, filed 4/26/2004, with respect to the rejection(s) of claim(s) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, new grounds of rejection are made.

8. Applicant's arguments with respect to claims 4, 5, 10-12 has been considered but is moot in view of the new ground(s) of rejection.

9. With regards to the Crocker reference, the examiner would like to give further detail to his interpretation of the prior art. Since the applicant is claiming a lumen instead of a guidewire tube, the examiner notes that the catheter has both a guidewire lumen within the perfusion lumen, since the guidewire will pass through the perfusion lumen. Since the perfusion lumen is collapsible, the guidewire lumen will also be capable of collapsing.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (703) 308-2698. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew DeSanto
Matthew DeSanto
Art Unit 3763
December 12, 2004

Nicola D. Lucchesi
NICOLA D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700